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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,783	09/23/2003	Miroslav Smriga	241244US0CONT	9560
22850	7590	08/24/2007		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER ROBERTS, LEZAH	
			ART UNIT 1614	PAPER NUMBER
			NOTIFICATION DATE 08/24/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

<b>Office Action Summary</b>	Application No. 10/667,783	Applicant(s) SMRIGA ET AL.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 24-26, 28-29 and 57-58 is/are withdrawn from consideration.
- 5) ☒ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-23, 27 and 30-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

This Office Action is in response to the Amendment filed May 29, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Election of Species and Restriction Requirement***

In order to make the record clear, the stress-induced disease, elected by Applicant with traverse in the reply filed on October 25, 2006 is anxiety disorders. The Examiner's clarification of the election does not affect the previously made rejections. Newly submitted claims 28-29 and 57-58 as well as previously withdrawn claims 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 25, 2006.

## ***Claims***

### **Claim Rejections - 35 USC § 112 – Scope of Enablement (Previous Rejection)**

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ameliorating, progress blocking and therapeutically treating one or more stress induced diseases, does not reasonably provide enablement for preventing one or more stress induced diseases. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection is withdrawn in regards to claims 1-23 and applied to claims 33-56.

Applicant has directed new claims 33-56 to preventing. Applicant argues the examples show subjects are fed a lysine-added diet prior to the various stresses loaded. The examples show the pharmaceutical compositions comprising lysine suppresses or prevents the instance of stress-induced diseases including anxiety disorders and those listed in the instant claims. Accordingly, Examiner's comments bridging pages 3-7 of the Office Action are based on pure conjecture. The specification clearly and unequivocally demonstrates that the claimed method can prevent the recited disorders. This argument is not persuasive.

It has not been shown by Applicant how the diet would affect the rats over a long period of time or with constant stress. Applicant only shows an instance of foot shock and not a continuous source of stress or cause of anxiety over a prolonged period of time. Therefore it cannot be determined if the lysine prevents the disorders but the results do show that the lysine compositions inhibit the disorders.

**Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)**

1) Claims 1-11, 13, 15-20 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaefer et al. (US 5,505,968). The rejection is maintained and further applied to claims 27, 30-43, 45, 47-52 and 54-56.

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Applicant argues in regards to Schaefer et al. that "anxiety disorders" of the present invention on page 3, line 9 and page 10, line 16, is defined as being "panic disorders and general anxiety disorders". Applicant further reminds the Examiner that Applicant is entitled to be their own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning. Applicant has amended the claims to include the clause: "wherein said anxiety disorders is one or more of panic disorders and general anxiety. This argument is not persuasive.

The reference discloses symptoms of antemortem stress, which include hypertension and anxiety. These symptoms fall into the categories of general anxiety or panic disorders because the animal is about to be slaughtered and therefore antemortem can be classified under panic disorders. It may also be concluded that antemortem stress is due to panic because the animal is aware it is in danger and therefore panics. Even if this is not the case, and this is not encompassed by Applicant's definition of anxiety disorders, the disorder of the reference could also be classified under emotion disorder since there appears to be no clear definition as to what this disorder encompasses. Applicant also does not appear to give specific examples of what is encompassed by the disorders as they apply to animals such as cattle.

**Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)**

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer et al. (US 5,505,968). The rejection is maintained and further applied to claim 44.

See Applicant's arguments and Examiner's answer supra.

**Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

Claims 1-17, 20-23, 27, 30-47 and 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 6,525,102) in view of Pitman (US 2004/0005311).

Chen discloses liquid pharmaceutical compositions comprising a polypeptide along with lysine, arginine or mixtures thereof to treat disorders including anxiety disorders (col. 19, lines 14-34). The compositions comprise the free form of the amino acids. They may also include acids glutamic and aspartic acid. The reference differs from the instant claims insofar it does not disclose a specific example of the compositions treating anxiety disorders.

Pitman discloses a dietary supplement composition comprising lysine. Patients that are lysine deficient took the compositions. Memory loss and anxiety symptoms decreased after the patients took the composition. Patients that continued taking a combination of lycopene and lysine continued to exhibit reduced symptoms (paragraph 0073). The amount of lysine taken per day ranges from 500 to 7500 mg, therefore based on a 75 kg patient, the dosage would range from 0.0067 to 0.1 g/kg

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encompassing claims 16-17. The compositions are orally delivered by way of gels, capsules, powders and/or tablets (paragraph 0007). The reference differs from the instant claims insofar as it does not specifically disclose anxiety disorders such as generalized anxiety disorder or panic attacks, but does disclose the compositions reduce anxiety.

It would have been obvious to one of ordinary skill in the art to use the compositions comprising lysine or mixtures of lysine, arginine and aspartic acid to treat the anxiety disorders of the primary reference motivated by the desire to use a composition comprising active agents that reduce anxiety as disclosed by the secondary reference.

Claims 1-23, 27, and 30-56 are rejected.

Claims 24-26, 28-29 and 57-58 are withdrawn.

No claims allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Lezah Roberts  
Patent Examiner  
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A handwritten signature in black ink, appearing to read "Lezah Roberts", written in a cursive style.

Frederick Krass  
Primary Examiner  
Art Unit 1614

A handwritten signature in black ink, appearing to read "Frederick Krass", written in a cursive style.